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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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20457	7590	03/22/2004	EXAMINER	
ANTONELLI, TERRY, STOUT & KRAUS, LLP 1300 NORTH SEVENTEENTH STREET SUITE 1800 ARLINGTON, VA 22209-9889			WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,846

Applicant(s)

ITO ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Regarding line 2 of claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Lines 3-4 of claim 1 are indefinite since it is not clear what these lines mean. Do these lines mean that a laboratory technician provides a set of operations to be performed with an automated analyzer and programs these operations into the analyzer in a certain order? See these same problems in claims 2 and 8.

On line 3 of claim 5, the phrase "on the outline of work" is indefinite and unclear since it is not known what is meant by this phrase. Does this phrase refer to an outline of one of the operations performed by the analyzer? What does the outline constitute?

On line 10 of claim 8, the "image for confirming" is indefinite since it is not clear what this refers to. Does this refer to the confirmation of a sample in the clinical analyzer?

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Miller.

Miller teaches of a computer interface module for use with an automated clinical analyzer. Miller also teaches of a method for controlling the operation of a plurality of interrelated automated analytical and sample preparation devices, and for obtaining information about the status of a given sample or operation in the analyzer. Miller teaches that such a method reduces the demand on the skills of an operating technician to perform complex programming and scheduling of assays or other analyzer functions. The method provides operation guidance on the clinical analyzer by allowing an unskilled technician to obtain particular information about the assay status of a given sample. The computer interface module allows a user to easily and quickly access a variety of control screens and status information display screens that describe the status of a plurality of interrelated automated devices used for sample preparation and clinical analysis of patient samples. The computer interface module has a first information display screen that is directly linked to a plurality of additional information

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display screens containing on-line information about the operational status of a plurality of interrelated automated devices, as well as information about the location of any specific sample in the analyzer and the status of clinical tests to be performed on the sample. The computer module comprises a visual touch screen that displays a menu including icons, scroll bars, boxes and buttons through which an operator may interface with the clinical analytical system. The computer interface module comprises a number of function specific buttons programmed to display detailed ancillary information for each function button so that additional information about the status and performance of the clinical system may be displayed. The clinical analytical system 10 includes at least one clinical analyzer 12 adapted to perform chemical assays on samples of biological fluids such as blood, serum, urine, etc. The analyzers 12 are equipped with a computer system 22 having a keyboard 23 and a number of touch-buttons displayed on a visual computer screen or module 24. The display screens include title bars 26, system names 28, screen titles 30 and status icons 32. All screens have a standard set of general function buttons 34 to provide a user with express navigation controls. The user can arbitrarily chose which buttons to press to see a desired display image of a desired clinical operation in the analyzer. A login screen 318 can be present in the computer interface module to invoke restrictions that may exist requiring a user to identify themselves to the module. This is similar to the navigation program icon recited in the instant claims that can be operated by only an approved laboratory technician. See lines 1-37 in column 3, columns 5 and 6, and all of the figures in Miller.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 3-4 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller. For a teaching of Miller, see previous paragraphs in this Office action.

Miller fails to teach that each operation in the clinical analyzer can be displayed on the computer interface module sequentially in the order in which each operation occurs to analyze a sample. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to change the computer interface module taught by Miller to sequentially display each operation performed by the clinical analyzer on the display screen of the module so as to lessen operator/technician interface or contact with the computer module by requiring the operator to only touch one screen on the module at the beginning of a sample analysis and then to merely observe each step of the analysis as the module displays each step in a sequential order.

9. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in view of Maus et al. For a teaching of Miller, see previous paragraphs in this Office action. Miller fails to teach that the computer interface module includes a voice as part of each display screen to vocally inform a user of the operation status of a particular analysis step in the analyzer.

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Maus et al teach of a health monitoring and diagnostic device, which includes therein a display device 34 for displaying the results of a diagnostic test such as cholesterol. The display 34 can be a liquid crystal display configured to display text lines. The display can also include a speaker 35 that conveys audible messages such as beeps, tones, recorded messages and simulated human voices to inform a user of test results. See lines 14-25 in column 12 and Figure 1A in Maus et al.

Based upon the combination of Miller and Maus et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include in the computer interface module taught by Miller a voice as part of each display screen to vocally inform a user of the operation status of a particular analysis step in the analyzer since Maus et al teach that it is known in the art to provide a voice as part of a display screen in a clinical analyzer to inform a user of sample results, errors, etc.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: JP 08-101204, JP 9-72911 and JP 9-72910 which teach of user interfaces in chemical analyzers that comprise computer display screens with a menu of touch buttons for selecting the display of certain settings and operations in the analyzers.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 15, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700